REMARKS

Reconsideration is requested.

Claims 23, 29, 31, 47 and 48 are pending.

The Section 103 rejection of claims 23, 29, 31, 47 and 48 over Baxter (U.S. Patent Application Publication No. 2002/0198236) in view of Cupps (U.S. Patent No. 6,486,190), is traversed. Reconsideration and withdrawal of the rejection are requested in view of the following distinguishing remarks.

The Examiner is understood to rely on Baxter for a teaching of a composition optionally containing ascorbyl palmitate as an antioxidant (see ¶[0666] of Baxter) in the optional treatment of CMT (see ¶[0548] of Baxter) to allegedly provide a *prima facie* case for obviousness. The secondary reference is relied upon by the Examiner to teach the use of ascorbic acid in a dose range of "about 50 to about 10,000 mg". See pages 5 and 6 of the Office Action dated March 17, 2009.

The cited art fails to teach or suggest the claimed methods. The cited art fails to teach or suggest the use of vitamin C or a derivative of the claims in an effective amount of the claimed methods. The ascorbyl palmitate of Baxter is used as an optional antioxidant and there is no suggestion in the cited art that vitamin C and the derivatives of the present claims could be successfully used in the presently claimed methods.

The applicants submit that ascorbic acid and the derivatives of the present claims are described in the present application as cAMP inhibitors. This property makes them relevant towards Charcot-Marie-Tooth (CMT) disease treatment. In Baxter, ascorbic

acid and ascorbyl palmitate are cited as examples of antioxidants that may be used in compositions of Baxter. Antioxidants are not described in Baxter as being relevant to CMT disease treatment but only as additive substances that may be added to compositions that may be used for a wide variety of diseases and conditions. No direct link is described in Baxter between CMT disease and antioxidants that may be optionally added to the compositions of Baxter, such as ascorbyl palmitate.

The present application describes the use of ascorbic acid and/or the claimed derivatives as the active substance of compositions for treatment of CMT disease.

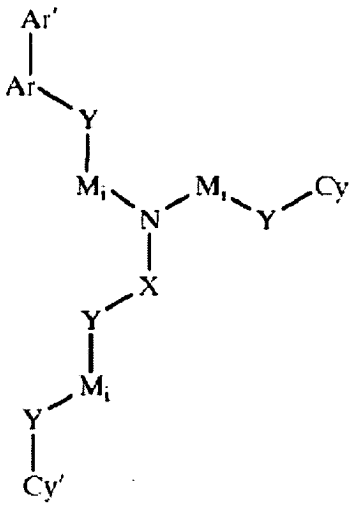
Baxter describes ascorbic acid and ascorbyl palmitate as examples of antioxidants optionally added to the compositions and not as active ingredients. The active ingredients of Baxter are described, for example, in ¶[0188] of Baxter. Ascorbic acid and ascorbyl palmitate are non indispensable components of the methods of Baxter.

Consequently, the use of ascorbic acid or ascorbyl palmitate as cAMP modulators, as active ingredients of compositions for treating CMT disease as claimed would not have been obvious from the cited art.

The cited secondary reference fails to cure these deficiencies of Baxter.

Baxter teaches the use of a compound, for example, of the following formula I:

Formula I



to allegedly treat or have an effect in, for example, any and all of the following

regulation of neural tissues, bone and cartilage formation and repair,

regulation of spermatogenesis,

regulation of smooth muscle,

regulation of lung, liver, urogenital organs (e.g., bladder), and other organs arising from the primitive gut,

regulation of hematopoietic function,

regulation of skin and hair growth, etc. (see ¶[0183] of Baxter);

treatment of disorders of, or surgical or cosmetic repair of, such epithelial tissues as skin and skin organs; corneal, lens and other ocular tissue; mucosal membranes; and periodontal epithelium,

treatment or prevention of a variety of damaged epithelial and mucosal tissues,

control wound healing processes, as for example may be desirable in connection with any surgery involving epithelial tissue, such as from dermatological or periodontal surgeries, including severe burn and skin regeneration, skin grafts, pressure sores, dermal ulcers, fissures, post surgery scar reduction, and ulcerative colitis (see ¶[0185] of Baxter);

effect the growth of hair, as for example in the treatment of alopecia whereby hair growth is potentiated (see ¶[0186] of Baxter);

treatment regimen for malignant medulloblastoma and other primary CNS malignant neuroectodermal tumors (see ¶[0187] of Baxter);

promoting, in vivo, proliferation or other biological consequences (see ¶[0188] of Baxter);

in cultures of neuronal stem cells, such as in the use of such cultures for the generation of new neurons and glia (see ¶[0514] of Baxter);

used to regulate the growth state in the culture, or where fetal tissue is used, especially neuronal stem cells, can be used to regulate the rate of differentiation of the stem cells (see ¶[0528] of Baxter);

used in vitro to regulate the differentiation of neural crest cells into glial cells, schwann cells, chromaffin cells, cholinergic sympathetic or parasympathetic neurons, as well as peptidergic and serotonergic neurons (see ¶[0529] of Baxter);

facilitate control of adult neurons with regard to maintenance, functional performance, and aging of normal cells; repair and regeneration processes in

chemically or mechanically lesioned cells; and treatment of degeneration in certain pathological conditions (see ¶[0530] of Baxter);

treatment protocol of (prevention and/or reduction of the severity of) neurological conditions deriving from: (i) acute, subacute, or chronic injury to the nervous system, including traumatic injury, chemical injury, vascular injury and deficits (such as the ischemia resulting from stroke), together with infectious/inflammatory and tumor-induced injury; (ii) aging of the nervous system including Alzheimer's disease; (iii) chronic neurodegenerative diseases of the nervous system, including Parkinson's disease, Huntington's chorea, amyotrophic lateral sclerosis and the like, as well as spinocerebellar degenerations; and (iv) chronic immunological diseases of the nervous system or affecting the nervous system, including multiple sclerosis,

Parkinson's disease (see ¶[0530] of Baxter);

Alzheimer's disease is associated with deficits in several neurotransmitter systems, both those that project to the neocortex and those that reside with the cortex,

dementia are associated with degeneration of the thalamus or the white matter underlying the cerebral cortex,

Huntington's disease,

Pick's disease (see ¶[0533] of Baxter);

Ballism,

neurogenic and myopathic diseases which ultimately affect the somatic division of the peripheral nervous system and are manifest as neuromuscular disorders,

amyotrophic lateral sclerosis,

Guillain-Barre

diseases which can be manifest as progressive bulbar palsies or spinal muscular atrophies,

disorders of the cerebellum which result in hypotonia or ataxia, such as those lesions in the cerebellum which produce disorders in the limbs ipsilateral to the lesion (see ¶[0534] of Baxter);

treatment of autonomic disorders of the peripheral nervous system, which include disorders affecting the enervation of smooth muscle and endocrine tissue (such as glandular tissue),

treatment of tachycardia,

treatment of atrial cardiac arrhythmias which may arise from a degenerative condition of the nerves innervating the striated muscle of the heart (see ¶[0536] of Baxter);

treatment of CNS trauma infarction,

treatment of infection (such as viral infection with varicella-zoster),

treatment of metabolic disease,

treatment of nutritional deficiency,

treatment of toxic agents (such as cisplatin treatment) (see ¶[0537] of Baxter);

generating nerve prostheses for the repair of central and peripheral nerve damage,

treatment of neoplastic or hyperplastic transformations such as may occur in the central nervous system,

treatment of malignant gliomas,

treatment of meningiomas,

treatment of medulloblastomas,

treatment of neuroectodermal tumors, and

treatment of ependymomas (see ¶[0539] of Baxter);

treatment or prophylaxis of disorders affecting the regulation of peripheral nerves,

treatment or prophylaxis of peripheral ganglionic neurons,

treatment or prophylaxis of sympathetic, sensory neurons,

treatment or prophylaxis of motor neurons,

treatments designed to rescue retinal ganglia, inner ear and acoustical nerves, and motor neurons, from lesion-induced death as well as guiding reprojection of these neurons after such damage caused by chemical or mechanical trauma, infection (such as viral infection with varicella-zoster), metabolic disease such as diabetes, nutritional deficiency, and toxic agents (such as cisplatin treatment) (see ¶[0540] of Baxter);

treatment of Refsum's disease,

treatment of abetalipoproteinemia,

treatment of Tangier disease,

treatment of Krabbe's disease,

treatment of metachromatic leukodystrophy,

treatment of Fabry's disease,

treatment of Dejerine-Sottas syndrome

treatment of Charcot-Marie-Tooth disease (see ¶[0543] of Baxter);

treatment of familial amyloidotic neuropathy and other related hereditary neuropathies (see ¶[0549] of Baxter);

treatment of hereditary porphyria, which can have components of peripheral neuropathy,

treatment of hereditary sensory neuropathy Type II (HSN II) (see ¶[0550] of Baxter);

prevention of diabetic neuropathies (see ¶[0551] of Baxter);

treatment of immune-mediated neuropathies (see ¶[0552] of Baxter);

treatment of acute motor neuropathy,

treatment of acute sensory neuropathy,

treatment of acute autonomic neuropathy,

treatment of Miller-Fisher syndrome (see ¶[0554] of Baxter);

treatment of chronic inflammatory demyelinating polyneuropathy (CIDP) (see ¶[0555] of Baxter);

treatment and prevention of chronic polyneuropathies with antibodies to peripheral nerves

treatment and prevention of demyelinating neuropathy associated with antibodies to the myelin associated glycoprotein (MAG),

treatment and prevention of motor neuropathy associated with antibodies to the gangliosides GM1 or GD1a,

treatment and prevention of sensory neuropathy associated with anti-sulfatide or GD1b ganglioside antibodies (see ¶[0556] of Baxter);

treatment of neuropathies associated with vasculitis or inflammation of the blood vessels in peripheral nerves,

treatment of rheumatoid arthritis,

treatment of lupus,

treatment of periarteritis nodosa,

treatment of Sjogren's syndrome,

treatment of polyneuritis,

treatment of mononeuritis,

treatment of mononeuritis multiplex (see ¶[0557] of Baxter);

treatment of brachial or lumbosacral plexitis,

treatment of ubosacral plexitis (see ¶[0558] of Baxter);

treatment of neuropathies associated with monoclonal gammopathies (see ¶[0559] of Baxter);

treatment of neuropathies associated with tumors or neoplasms,

treatment of paraneoplastic neuropathy,

management of sensory neuropathy associated with lung cancer,

treatment of neuropathies associated with multiple myeloma,

treatment of neuropathies associated with Waldenstrom's macroglobulemia,

treatment of neuropathies associated with chronic lymphocytic leukemia,

treatment of neuropathies associated with B-cell lymphoma,

treatment of patients with cancers where neuropathy is a consequence of local irradiation or be caused by medications such as vincristine and cisplatin (see ¶[0560] of Baxter);

treatment of neuropathies associated with amyloidosis (see ¶[0561] of Baxter);

treatment of neuropathies caused by infections,

treatment of peripheral neuropathies caused by infection of the peripheral nerves,

treatment of peripheral neuropathies caused by the AIDS virus,

treatment of peripheral neuropathies caused by HIV-I,

treatment of peripheral neuropathies caused by cytomegalovirus,

treatment of peripheral neuropathies caused by Herpes zoster,

treatment of peripheral neuropathies caused by poliovirus,

treatment of peripheral neuropathies caused by Hepatitis B or C infections (see ¶[0562] of Baxter);

treatment of neuropathies caused by leprosy,

treatment of neuropathies caused by Lyme disease,

treatment of neuropathies caused by trypanosomiasis (see ¶[0563] of Baxter);

treatment of neuropathies caused by nutritional imbalance,

treatment of neuropathies caused by vitamin B12 deficiency,

treatment of neuropathies caused by vitamin B1 (thiamine) deficiency,

treatment of neuropathies caused by vitamin B6 (pyridoxine) deficiency,

treatment of neuropathies caused by vitamin E,

treatment of neuropathies caused by megadoses of vitamin B6 (see ¶[0564] of Baxter);

treatment of neuropathies arising in kidney diseases (see ¶[0565] of Baxter);

treatment of hypothyroid neuropathies (see ¶[0566] of Baxter);

treatment of neuropathies caused by alcohol,

treatment of neuropathies caused by toxins (see ¶[0567] of Baxter);

treatment of neuropathies caused by drugs,

treatment of neuropathies caused by vincristine,

treatment of neuropathies caused by cisplatin

treatment of neuropathies caused by nitrofurantoin,

treatment of neuropathies caused by amiodarone,

treatment of neuropathies caused by disulfiram,

treatment of neuropathies caused by ddC,

treatment of neuropathies caused by ddI,

treatment of neuropathies caused by dapsone (see ¶[0568] of Baxter);

treatment of neuropathies caused by trauma or compression,

treatment of carpal tunnel syndrome,

treatment of cervical or lumbar radiculopathies (sciatica),

treatment of nerve compression in the elbows, armpits, and the back of the knees (see ¶[0568] of Baxter);

treatment or prophylaxis of disorders afflicting muscle tissue (see ¶[0571] of Baxter);

treatment of atrophy,

treatment of wasting,

treatment of skeletal muscle atrophy and cardiac muscle atrophy,

treatment of normal aging,

treatment of disuse atrophy,

treatment of wasting

treatment of cachexia,

treatment of hypertension,

treatment of glucose intolerance

treatment of diabetes,

treatment of dyslipidemia,

treatment of atherosclerotic cardiovascular disease,

treatment of. muscular myopathies such as muscular dystrophies (see ¶[0572] of Baxter);

treatment of muscular dystrophies,

treatment of cardiac cachexia, emphysema,

treatment of leprosy,

treatment of malnutrition,

treatment of osteomalacia,

treatment of child acute leukemia,

treatment of cachexia,

treatment of cancer cachexia (see ¶[0574] of Baxter);

liver repair subsequent to a partial hepatectomy (see ¶[0593] of Baxter);

control or regulate the proliferation and/or differentiation of pancreatic tissue both in vivo and in vitro (see ¶[0595] of Baxter);

treatment of hyperplastic and neoplastic disorders effecting pancreatic tissue, particularly those characterized by aberrant proliferation of pancreatic cells (see ¶[0597] of Baxter);

in vitro generation of skeletal tissue (see ¶[0601] of Baxter);

restoring cartilage function to a connective tissue (see ¶[0602] of Baxter);

prosthetic device therapies (see ¶[0605] of Baxter);

enhancing attachment of prosthetic devices (see ¶[0609] of Baxter);

generating bone (osteogenesis) at a site in the animal where such skeletal tissue is deficient (see ¶[0610] of Baxter);

regulating spermatogenesis (see ¶[0611] of Baxter);

treating disorders afflicting epithelial tissue (see ¶[0612] – [0619] of Baxter);

treating or preventing gastrointestinal diseases (see ¶[0620 of Baxter);

By the present Examiner's interpretation of Baxter, the reference allegedly teaches administering an effective amount of vitamin C or a derivative thereof of the present claims to allegedly treat or have an effect in, for example, any and all of the above. The applicants submit, with due respect, that the cited combination of art fails to teach or suggest the claimed invention.

As stated in KSR Int'l. Co. v. Telejlex Inc., 550 U.S. 398,418 (2007), "rejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness" (quoting In re Kahn, 441 F.3d 977, 988 (Fed. Cir. 2006)). The Examiner has not provided the required articulated reasoning with rational underpinning.

Withdrawal of the Section 103 rejection is requested.

The claims are submitted to be in condition for allowance and a Notice to that effect is requested. The Examiner is requested to contact the undersigned, preferably by telephone, in the event anything further is required in this regard.

Respectfully submitted,

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